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WIPO

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT24454	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IT00/00309	International filing date (day/month/year) 21/07/2000	Priority date (day/month/year) 21/07/1999
International Patent Classification (IPC) or national classification and IPC A61K31/00		
Applicant STRUMILLO DJACZENKO, Maria et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 4 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 15/02/2001	Date of completion of this report 19.04.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Winger, R Telephone No. +49 89 2399 8129 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IT00/00309

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-9 as originally filed

Claims, No.:

1-25 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IT00/00309

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-25
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-25
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	

2. Citations and explanations
see separate sheet

Re Section V: Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Prior Art: Reference is made to the following documents cited in the International Search Report

D1: AMERICAN FAMILY PHYSICIAN, 1994, 50/1, 89-96

D2: US-A-5 043 357

D3: EP-A-0 059 441

D4: US-A-4 902 501

Document D1 discloses salicylic acid and trichloroacetic acid separately for treating acne / as exfoliant (p 93). Document D2 discloses topical virucidal compositions containing an alcohol and a carboxylic acid (claims 1 and 17). Document D3 discloses topical compositions (claims 1, 5, 11) comprising a terpene (e.g. menthol) and a ketocarboxylic acid for the treatment of cutaneous injuries (p 4). Document D4 discloses a pharmaceutical composition comprising cholestyramin, antimicrobial agents (hydroxy benzoic acids) in a polymeric suspending/coating agent.

2. Novelty and Inventive Step(Article 33(2) and (3) PCT):

Claim 1 relates to a pharmaceutical composition for topical use comprising in a suitable polymer trichloroacetic acid, 2-hydroxy benzoic acid and (1 α ,2 β ,5 α)-5-methyl-2-(1-methylethyl)cyclohexanol.

As none of the prior art documents disclose a corresponding composition, the subject-matter of claims 1 and dependent claims 2-18 seems to be novel.

In addition, as there is no indication in the prior art to combine these substances and as its (painless) application for the treatment of burns has been shown, the subject-matter of claims 1-18 also seems to be inventive.

For the same reasons, claims 19-25, relating to a process for the preparation of said composition, seems to be novel and inventive.

3. Industrial Applicability (Article 33(4) PCT):

The subject-matter of the claims concerns pharmaceutical compositions and a process for their preparation which are industrially applicable.